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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO
09/697,379	10/26/2000	Jonathan Edward Lightner	BB-1043-US-NA-DIV	8713

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E I DU PONT DE NEMOURS AND COMPANY
LEGAL PATENT RECORDS CENTER
BARLEY MILL PLAZA 25 1128
4417 LANCASTER PIKE
WILMINGTON, DE 19805

EXAMINER
MCELWAIN, ELIZABETH F

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 10/08/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/697,379	Applicant(s) LIGHTNER ET AL.
	Examiner Elizabeth McElwain	Art Unit 1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 July 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,9,10,13,15-20 and 24-59* is/are pending in the application.

4a) Of the above claim(s) *9,10,13,15-20,24-32 and 45-59* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 33-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1☐ Certified copies of the priority documents have been received.

2☐ Certified copies of the priority documents have been received in Application No. _____

3☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 5
4)☐ Interview Summary (PTO-413) Paper No(s). _____
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: _____

Claims 1, 9, 10, 13, 15-20 and 24-59 are pending.

Applicant's election without traverse of Group I, claims 1 and 33-44, in Paper No. 7 is acknowledged. Applicants pointed out that claim 34 was improperly included in Group III, but is properly included in Group I. Therefore, claim 34 is withdrawn from non-elected Group III.

In addition, in response to applicants traversal, the supplemental restriction of March 4, 2002 has been withdrawn.

Claims 9, 10, 13, 15-20, 24-32 and 45-59 are withdrawn from consideration, as drawn to non-elected inventions.

Claims 1 and 33-44 are examined on the merits.

The Declarations filed July 16, 2002 have been received. It is noted that in the parent application an application data sheet was provided with the declaration, which provided the post office address of each inventor. However, no application data sheet has been provided in the present application. Therefore, the following statement of defective oath is set forth.

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It does not identify the city and either state or foreign country of residence of each inventor. The residence information may be provided on either on an application data sheet or supplemental oath or declaration.

It does not identify the mailing or post office address of each inventor. A mailing or post office address is an address at which an inventor customarily receives his or her mail and may be either a home or business address. The mailing or post office address should include the ZIP Code designation. The mailing or post office address may be provided in an application data sheet or a supplemental oath or declaration. See 37 CFR 1.63(c) and 37 CFR 1.76.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 33, and claims 34-41 dependent thereon, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 33 is indefinite in the recitation of "desaturase-related", since it is unclear what this would encompass. Therefore, this phrase does not set forth the metes and bounds of the claimed invention.

Claim 33 is also indefinite in the recitation of "a part thereof", since this could encompass as little as one nucleotide. In addition, this phrase is recited twice, and in the first line of part b), it is unclear what nucleic acid it would be a part of.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 33-44 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 6,372,965. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims overlap in subject matter with the patented claims, which are both drawn to isolated nucleic acids encoding fatty acid desaturase genes that are similar in sequence to SEQ ID Nos: 1, 3, 5, 7, 9, 11 and 15. Therefore, the present claims are obvious in view of the claims of U.S. Patent No. 6,372,965.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 33-44 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are drawn to nucleic acid sequences that encode a desaturase or desaturase-related protein that is at least 50% identical to SEQ ID NO: 1, 3, 5, 7, 9, 11, or 15, or to nucleic acid sequences that are at least 80% identical to nucleic acid sequences that encode SEQ ID NO: 1, 3, 5, 7, 9, 11, or 15. The claims are also drawn to nucleic acid fragments that are useful in antisense or co-suppression of an endogenous desaturase, including parts of said sequences. Also, claims are drawn to a nucleic acid fragment that encodes an enzyme that catalyzes a reaction at carbon positions 6 and 7 numbered from the methyl end of an 18 carbon long fatty acyl chain. In addition, claims are drawn to methods of modifying oil in plant, and plants and seeds transformed with said sequences. However, the specification does not disclose what structural features would be conserved in the claimed sequences that would result in the claimed enzyme activity that is desaturase, desaturase-related or that catalyzes a reaction at carbon positions 6 and 7 numbered from the methyl end of an 18 carbon long fatty acyl chain. Nor does the specification describe the structural features required for a nucleic acid fragment to confer antisense or co-suppression on an endogenous desaturase gene. Applicants are

claiming a genus of sequences, yet there is no description of the structural features that define the genus.

See *University of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ 2d 1398 (Fed, Cir. 1997), where it states:

> "The name cDNA is not in itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA . . . Accordingly, the specification does not provide a written description of the invention . . ."

Therefore, given the lack of written description in the specification with regard to the structural and physical characteristics of the claimed compositions, one skilled in the art would not have been in possession of the genus claimed at the time this application was filed.

Claims 1 and 33-44 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims to a nucleic acid that encodes a plant delta-12 fatty acid desaturase that encodes a protein having at least 50% identity to the sequences of SEQ ID NO: 1, 3, 5, 7, 9, 11 or 15; and while being enabling for claims to a nucleic acid that encodes a plant delta-12 fatty acid desaturase that has the limitations of claim 42, does not reasonably provide enablement for a nucleic acid that encodes any desaturase or desaturase-related gene, or antisense or co-suppression fragment that will reduce expression of any endogenous desaturase gene, any of these having sequence similarity to SEQ ID NO: 1, 3, 5, 7, 9, 11 or 15; or to any

gene that encodes an enzyme that catalyzes a reaction at carbon positions 6 and 7 numbered from the methyl end of an 18 carbon long fatty acyl chain, without specifying delta-12 desaturase activity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are drawn to nucleic acid sequences that encode a desaturase or desaturase-related protein that is at least 50% identical to SEQ ID NO: 1, 3, 5, 7, 9, 11, or 15, or to nucleic acid sequences that are at least 80% identical to nucleic acid sequences that encode SEQ ID NO: 1, 3, 5, 7, 9, 11, or 15. The claims are also drawn to nucleic acid fragments that are useful in antisense or co-suppression of an endogenous desaturase, including parts of said sequences. Also, claims are drawn to a nucleic acid fragment that encodes an enzyme that catalyzes a reaction at carbon positions 6 and 7 numbered from the methyl end of an 18 carbon long fatty acyl chain. In addition, claims are drawn to methods of modifying oil in plant, and plants and seeds transformed with said sequences. However, the specification only discloses sequences that encode fatty acid delta-12 desaturases. The specification does not disclose other desaturases or methods of evaluating sequences for other desaturase activities. In addition, the specification does not teach what fragments would confer antisense or co-suppression activity on endogenous desaturase genes.

Sequence homology is not sufficient to predict function of encoded sequences. See the teachings of Doerks (TIG 14, no. 6: 248-250, June 1998), where it states that computer analysis of genome sequences is flawed, and "overpredictions are common because the highest scoring

database protein does not necessarily share the same or even similar functions" (the last sentence of the first paragraph of page 248). Doerks also teaches homologs that did not have the same catalytic activity because active site residues were not conserved (page 248, the first sentence of the last paragraph). In addition, Smith et al (Nature Biotechnology 15:1222-1223, November 1997) teach that "there are numerous cases in which proteins of very different functions are homologous" (page 1222, the first sentence of the last paragraph). Also, Brenner (TIG 15, 4:132-133, April 1999) discusses the problem of inferring function from homology, stating that "most homologs must have different molecular and cellular functions" (see the second full paragraph of the second column of page 132, for example). Furthermore, Borks (TIG 12, 10:425-427, October 1996) teaches numerous problems with the sequence databases that can result in the misinterpretation of sequence data.

More specifically, identification of related sequences that will encode enzymes having a specific activity is particularly problematic in the enzymes involved in modifying fatty acids, and cannot be determined merely by similarity of DNA or amino acid sequences. Van de Loo et al teach that sequences encoding fatty acid hydroxylase activity are highly similar to other sequences that do not encode a hydroxylase, but instead encode a fatty acyl desaturase (see the abstract, at least). In fact, Broun et al teach that a change in only four amino acids will convert a desaturase gene to a hydroxylase gene (see the abstract, at least). Thus, if sequences are identified only by similarity to other sequences that are known, one cannot conclude on this basis alone that these sequences also will encode a protein having said activity without additional evidence of the

functionality or more knowledge of the particular structural features that are required for conferring this function.

Therefore, it would require undue experimentation to identify which other sequences encompassed by the claims have desaturase activity, desaturase related activity, antisense or co-suppression activity, and furthermore, what type of desaturase activity that would be. It would also require undue experimentation to determine what type of activity the nucleic acids of claim 42 would confer. Given the uncertainty of predicting the activity of an enzyme by sequence homology, as stated above; the absence of guidance with regard to what amino acid sequences would would confer the claimed activity; the lack of working examples of other sequences encompassed by the claims that encode other desaturases and antisense or co-suppression fragments; and given the high level of skill in the art and the state of the prior art, which did not teach what structural elements are required for all desaturase and desaturase-related enzymes, it would require undue experimentation by one skilled in the art to make and/or use the invention, as broadly claimed.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States

Claims 33-35 and 37-41 are rejected under 35 U.S.C. 102(b) as being anticipated by Wada et al (Nature 347, 13 September 1990, pp 200-203).

The claims are drawn to nucleic acid sequences that encode a desaturase or desaturase-related protein that is at least 50% identical to SEQ ID NO: 1, 3, 5, 7, 9, 11, or 15, or to nucleic acid sequences that are at least 80% identical to nucleic acid sequences that encode SEQ ID NO: 1, 3, 5, 7, 9, 11, or 15. The claims are also drawn to nucleic acid fragments that are useful in antisense or co-suppression of an endogenous desaturase, including parts of said sequences. Also, claims are drawn to a nucleic acid fragment that encodes an enzyme that catalyzes a reaction at carbon positions 6 and 7 numbered from the methyl end of an 18 carbon long fatty acyl chain. In addition, claims are drawn to methods of modifying oil in plant, and plants and seeds transformed with said sequences.

Wada et al teach a nucleic acid encoding a desaturase transformed into a plant, which modifies oil production in the plant, wherein parts of said sequence would be at least 80% identical to those encoding any of SEQ ID NO: 1, 3, 5, 7, 9, 11 or 15 or would encode a protein at least 50% identical to any of these, given that there is no limitation provided regarding what would constitute a part of the nucleic acid fragment.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth F. McElwain whose telephone number is (703) 308-1794. The examiner can normally be reached on Monday through Friday from 8:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218. The fax phone number for this Group is (703) 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Any inquiry of a general nature or relating to the status of this application should be directed to the legal analyst, Gwendolyn Payne, whose telephone number is (703) 305-2475, or to the Group receptionist whose telephone number is (703) 308-0196.

Elizabeth F. McElwain, Ph.D.
September 27, 2002